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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,174	10/23/2003	Kenneth L. Rinehart	4126-4012	2597
27123	7590	12/15/2004	EXAMINER	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/693,174

Applicant(s)

RINEHART ET AL.

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/18/04</u> .   | 6) <input type="checkbox"/> Other: ____                                     |

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group I, claims 19-35 and the method of treating cancer as the species of method of use in the reply filed on November 4, 2004 is acknowledged. The traversal is on the ground(s) that the Examiner has failed to show that a serious burden exists in examining the full scope of the invention as claimed. This is not found persuasive because the inventions have acquired a separate status in the art as shown by their different classification and the compounds of Group II are not of the same scope as the compounds in the composition and method of Group I. The search required for Group I is not required for Group II and it would be a serious burden exists in examining the full scope of the invention as claimed.

The requirement is still deemed proper and is therefore made FINAL.

Claims 36 [note earlier typographical error]-38 have been withdrawn as not reading on the elected invention. Claim 31 is

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Objections***

The title of the invention is not descriptive of the invention as now claimed. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is not descriptive of the invention as now claimed. A new abstract on a separate sheet is required.

### ***Claim Rejections - 35 USC § 112***

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no description in the specification or guidance for the artisan as to what compounds may form prodrugs of the recited long-chain, straight-chain 2-amino-3-hydroxyalkane compound of claim 19.

The specification discloses only compounds used to treat cancer as the "additional drug for combination therapy," and that the intent is to form compositions for the treatment of cancer (-ages 6-7), while the intent in claims 32 and 33 is to include any and all additional drugs.

The specification does not disclose how the Rho protein activity is modulated by spisulosine (as recited in claim 31). It says on page 8, "By affecting (reducing) the levels of microfilaments in the cell, via an (inhibitory) effect on Rho, spisulosine **may**

[emphasis added] serve to limit the development of cancer via an effect on the cell cytoskeleton.”

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether the Rho protein activity is inhibited or enhanced.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 381 514. '514 (Fig. 1, p. 3-5) discloses a composition comprising the instant compound when it is a prodrug of the recited 2-amino-3-hydroxyalkane compound when the carbon chain is C<sub>18</sub>.

Claims 26-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 381 514. '514 (Fig. 1, p. 3-5) discloses a composition comprising the instant compound when it is a prodrug of the recited 2-amino-3-hydroxyalkane compound when the carbon chain is C<sub>18</sub> and a method of using it to treat cancer. Claim 28 appears to differ over '514 in reciting a method of controlling tissue and tumor vascularization. Claim 31 recites a method of altering Rho protein activity. However, these would be

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inherent, since they are the mechanism of action by which compound works in treating cancer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-23, 25 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 381 514. '514 (Fig. 1, pp. 3-5) discloses a composition comprising the instant compound when it is a prodrug of the recited 2-amino-3-hydroxyalkane compound when the carbon chain is C<sub>18</sub>. Claim 23 differs over '514 in reciting that the carbon chain is C<sub>20</sub>-C<sub>24</sub>, a homolog of the compounds disclosed in Fig. 1. However, because the characteristics normally possessed by members of a homologous series are principally the same, varying gradually from member to member, one of ordinary skill in the art would know what to expect in adjacent members so that a mere difference in degree is not the marked superiority which ordinarily removes the unpatentability of homologues of old substances. In re Henze 85 USPQ 261.

Claim 25 differs over '514 in reciting the parent compound of Formula I. However, in the absence of a showing of unexpected results, it would be obvious to one of ordinary skill in the art that the prodrug forms the parent compound in the body.

Claim 32 differs over '514 in reciting an additional drug. However, no unobviousness is seen in adding an additional drug to the composition, since combination drug therapy is well known in the cancer art.

Claims 29-30, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 381 514. '514 (Fig. 1, pp. 3-5) discloses a composition comprising the instant compound when it is a prodrug of the recited 2-amino-3-hydroxyalkane compound when the carbon chain is C<sub>18</sub> and a method of using it to treat cancer.

Claims 29-30 differs over '514 in reciting that the carbon chain is C<sub>20</sub>-C<sub>24</sub>, a homolog of the compounds disclosed in Fig. 1. However, because the characteristics normally possessed by members of a homologous series are principally the same, varying gradually from member to member, one of ordinary skill in the art would know what to expect in adjacent members so that a mere difference in degree is not the marked superiority which ordinarily remove the unpatentability homologues of old substances. In re Henze 85 USPQ 261.

Claim 33 differs over '514 in reciting an additional drug. However, no unobviousness is seen in adding an additional drug to the method of use, since combination drug therapy is well known in the cancer art.

Claim 35 differs over '514 in reciting the parent compound of Formula I. However, in the absence of a showing of unexpected results, it would be obvious to one of ordinary skill in the art that the prodrug forms the parent compound in the body.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 381 514. '514 (Fig. 1, pp. 3-5) discloses a composition comprising the instant compound when it is a prodrug of the recited 2-amino-3-hydroxyalkane compound when the carbon chain is C<sub>18</sub>. The instant claim differs over '514 in reciting a method of preparing a pharmaceutical composition by combining a 2-amino-3-hydroxyalkane with a pharmaceutically acceptable carrier. However, '514 recites compositions comprising a prodrug of the recited compound with a pharmaceutically acceptable carrier. This would be obvious to the artisan since no unobviousness is seen in merely mixing two ingredients, which is well-known in the pharmaceutical art.

Claim 34 further differs over '514 in reciting the parent compound of Formula I. However, in the absence of a showing of unexpected results, it would be obvious to one of ordinary skill in the art that the prodrug forms the parent compound in the body.

#### ***Information Disclosure Statement***

Palameta et al was not received.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).



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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent Serial No 6,800,661. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method of treating cancer using a long-chain, straight-chain 2-amino-3-hydroxyalkane compound is rendered obvious by the method of '661 which is to treating one or more tumors using a composition comprising the instant compound.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


The official fax number is 571-273-8300.

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Rebecca Cook

A handwritten signature in cursive script, appearing to read 'Rebecca Cook', written in black ink.

Primary Examiner

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December 13, 2004